PSI Research Ethics Program
QUESTIONS TO ANSWER BEFORE DEVELOPING A SUBMISSION FOR ETHICAL REVIEW

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- *Does My Activity Require Ethical Review?* PSI requires ethical review for all protocols that meet the specific, regulatory definition of research and human subject. The document "PSI Guidelines for Deciding Whether an Activity Requires REB Review" provides guidance on deciding whether a study is research or non-research. If, after reading it, a researcher is still struggling with this determination, he/she should consult the Regional Researcher and/or request help from the REP Manager by submitting the form entitled Request for Determination of Research or Non-Research.

- *Is PSI Engaged in Research?* If an activity is research, it is important to determine if PSI, as an institution, is engaged in research. If PSI staff or researchers are leading the research, then PSI is clearly "engaged in research". However, if PSI is collaborating with other institutions and/or completing specific tasks in a much larger research protocol, it can be difficult to determine if PSI is engaged in research. In brief, PSI is engaged in research if PSI intervenes or interacts with living individuals for research purposes or obtains individually identifying information for research purposes. If PSI is engaged in research, then ethical review is required. For guidance on deciding if PSI is "engaged in research", contact the Regional Researcher or the PSI/REP Manager or consult this guidance (http://www.hhs.gov/ohrp/policy/engage08.html).

- *Which ethical review board should review the submission?* PSI/REB policy states that a research protocol must be reviewed by the PSI/REB or an alternate committee registered with the U.S. Government. The alternate committees may operate at the local level or may be run by a collaborating institution or university. The R&M document entitled "Roles and Responsibilities for Study Review and Human Subjects Toolkit explains how researchers should document the approval process when alternate committees are used. Each board has its own submission forms, procedures and timelines, so the decision about which board to use should be made early on in the planning process.

- *Which PSI staff should write and review the submission?* The R&M toolkit "Roles and Responsibilities for Study Review and Human Subject Protections" provides step by step instructions about who is responsible for developing the submission materials and study design, reviewing the materials and submitting the package to either the PSI/REB or an alternate committee. One of the principle reasons for delay in the PSI/REB approval process is due to research staff not following the correct steps for writing and reviewing submissions, so it is critical to follow these guidelines to ensure an efficient review.